2. A statement that all of the assurances and information you provided in the approved waiver as required by 42 CFR 441.302(a) - (f) remain in effect, including any amendments approved by HCFA. If the assurances or other documentation provided are to be implemented differently under the renewed waiver, the changes must be described. This includes any changes in licensure or certification requirements for providers of home and community-based services and any changes made in the level of care assessment process or team. If the evaluation instrument to be used under the extended waiver differs from the instrument approved in the original waiver, a copy must be submitted. The same applies to the Medicaid Agency's safeguards to protect the health and welfare of waiver recipients.

3. Average per capita expenditure estimates, as described in 42 CFR 441.303(f), for each year of the renewed waiver. Submit individual formulas for each year for each level of care covered in the waiver (hospital, NF, ICF/MR), as well as a combined formula for each year. Additionally, submit current data on the actual cost of the individual home and community-based services to support the revised cost data contained in the formulas. Data in the per capita expenditure estimate formula must be expressed in terms of average annual cost per unduplicated recipient. This data must be consistent with data supplied on Forms HCFA-372/372(S) and HCFA-2082. (See §4442.8 for further instructions about these requirements.)

4. A statement that the same services described in the original waiver will be provided under the renewed waiver. Describe any changes in the service package or in the manner in which the services are to be provided. Submit standards for providers or facilities of any new services not included in the approved waiver. See §4442.4 for further instructions about these requirements.

5. A statement that the eligibility requirements and procedures described in the original waiver remain in effect under the renewed waiver. Describe any changes in the requirements or procedures which are being made.

6. Documentation to support a conclusion that you have taken appropriate corrective action to resolve problem areas identified through Federal monitoring activities.

7. Documentation to support a conclusion that the waiver program was cost effective or cost neutral during the previous waiver period. Renewal requests are not approved unless you have submitted:

- The required Form HCFA-372/372(S) for all but the final year of the waiver period and accepted Forms HCFA-372/372(S) for all but the last 2 years of the waiver period; and

- The results of the independent assessment of the waiver if you opted to have one performed. (See §4442.11.) The results of the assessment must be submitted to HCFA at least 90 days prior to the expiration of the approved waiver period and cover all but the final year of the waiver.

NOTE: HCFA exercises its authority to require that any waiver elements (e.g., services, eligibility criteria, fiscal data, etc.) approved in the original waiver request but subsequently determined to be impermissible under the statute or regulations be appropriately modified or deleted from the request prior to granting renewal. Therefore, the standards applied by HCFA in reviewing renewal requests do not differ significantly from that currently applied to initial waiver requests.

You may submit an entire copy of your waiver to request renewal of the program. However, this may delay consideration of the request. In situations where the waiver has been subject to amendments or was substantially revised during the initial approval process, HCFA may require submission of the entire waiver renewal proposal if it believes the approved waiver document has become unacceptably complex due to multiple revisions.

E. Content of Subsequent Waiver Renewal Requests.--Requests for second and subsequent renewals of waiver programs must contain the same information as an initial request. (See §§4442-4442.11.) Because second and subsequent renewals will take place at 5 year intervals, it is necessary that you submit the entire waiver proposal to assure that the waiver file accurately represents all revisions and amendments to the program which have taken place. You are exempt from this requirement on second and subsequent renewals if the renewal contains no changes to the approved waiver and no amendments have been made since the waiver was initially approved.

4445. HOME AND COMMUNITY-BASED SERVICES - AMENDMENTS

A. When an Amendment Is Required.--An amendment is required when a change in a waiver results in the waiver document no longer accurately reflecting the policies and procedures in the approved waiver document. The amendment usually must be approved by HCFA prior to the implementation of the proposed change. However, there are instances where amendments may be approved with a retroactive effective date as far back as the beginning of the waiver year in which it is submitted. Some examples of such situations would be revisions to the cost estimates, deletion of a waiver service, or compliance with revised State rules or regulations.

B. Submission.--An amendment request is processed like a waiver request. (See §4441 for process related instructions.) Amendment requests consist of two types: substantive requests and technical requests.

It is to your benefit to submit technical amendments under separate cover from substantive amendments. This maximizes the likelihood of approval without the delay caused by a request for additional information, which is often necessary on substantive amendments.

1. Technical Amendment.--A technical amendment is any amendment in which the change has no impact on cost or utilization of services (directly or indirectly). Such amendments must be accompanied by specific assurances that there will be no change to the costs, utilization of services, or number of persons served by the waiver, and an explanation of why this is so.

2. Substantive Amendment.--A substantive amendment is any amendment which directly or indirectly affects any of the values under which the waiver was shown to be cost effective or cost neutral at its approval. Therefore, in most cases, a change in any of the following would constitute a substantive amendment:

a. Any change in the number of waiver recipients served, the cost of waiver services, or the mix of beneficiary groups or services provided.

NOTE: Although the C x D FFP limitation has been eliminated effective for waiver applications (or renewals) filed before, on, or after April 7, 1986 and for services furnished on or after August 13, 1981, if you anticipate substantial changes in your cost estimates, submit these changes in the form of an amendment to your waiver. This amendment should provide a complete explanation of the reasons for the change and recomputed cost effectiveness or cost neutrality formulas documenting the continued cost effective or cost neutrality of the waiver program.

b. Changes to the definition of services.

c. Changes to who is eligible to participate.

d. Changes to who may provide services.

e. Changes in health and safety standards for providers which would increase the cost of services (e.g., change in the number of individuals who can be cared for in a foster home).

f. Changes necessary to implement specific statutory provisions, e.g., the 1985 COBRA provisions pertaining to habilitation services or maintenance of income standards and the 1997 BBA provisions which deleted the requirement that individuals be discharged from an NF or ICF/MR to be eligible for expanded habilitation.

Requests for substantive amendments must be accompanied by a revised formula which demonstrates that the waiver will remain cost effective or cost neutral with the amendment. The formula format to be used must comply with the formula given in 42 CFR 441.303(f) for amendments approved on or after August 24, 1994.

4446. HOME AND COMMUNITY-BASED SERVICES - TERMINATIONS

A. Voluntary Terminations.--When you choose to voluntarily terminate your home and community-based waiver before the expiration of the waiver period, you must notify HCFA in writing 30 days before terminating services to recipients. You must also notify recipients of services under the waiver in accordance with 42 CFR 431.210, 30 days before terminating services.

B. Involuntary Terminations

1. Cause for Involuntary Termination.--If HCFA finds that you have violated any of the assurances made in your approved waiver request, or are otherwise in violation of Federal regulations applicable to home and community-based waivers, you will be given a notice of HCFA's findings and an opportunity for a hearing to rebut those findings. If HCFA determines that you are not in compliance with the regulations after the notice and any hearing, HCFA has the discretion to terminate the waiver. HCFA will, in making this decision, take into account any information you

have submitted with respect to why the waiver should not be terminated, including corrective action plans and evidence of corrective action undertaken.

Circumstances which may, at HCFA's discretion, result in involuntary termination of a waiver include but are not limited to cases in which:

a. HCFA finds that your actual total expenditures for home and community-based and other Medicaid services provided to individuals under the waiver exceed, for any year of the waiver period, the amount that would be incurred by Medicaid for these individuals in a hospital, NF, or ICF/MR without a waiver.

b. The health and welfare of waiver recipients have been jeopardized.

c. You have not maintained accurate financial records documenting the cost of waiver services.

d. You have failed to complete satisfactorily required HCFA reports needed to evaluate the operation of the waiver.

e. You have failed to comply with any other requirement established for the home and community-based waiver program in Federal regulations.

f. You have operated the waiver in a manner which is grossly inconsistent with the waiver as approved by HCFA.

2. Process.--When HCFA believes that termination of a waiver is warranted, HCFA will advise you in writing of its findings and will offer you an opportunity for a hearing to rebut the findings. Procedures specified at 45 CFR Part 213 are applicable to your requests for hearings on terminations.

Where the hearing results in termination of the waiver, or you choose to accept termination without a hearing, you must notify recipients of services under the waiver in accordance with 42 CFR 431.210, and must notify them 30 days before terminating services.

THE NEXT PAGE IS 4-487.

4460. NURSE AIDE REGISTRY

Establish and maintain a nurse aide registry of individuals who have successfully completed a nurse aide training and competency evaluation program or competency evaluation program approved by the State or have been deemed to have completed a nurse aide training and competency evaluation program or have had the competency evaluation requirement waived. (See §2504.)

A. Registry Function.--Ensure that the nurse aide registry:

- Lists all individuals who have successfully completed a nurse aide training and competency evaluation program or competency evaluation program approved by the State;
- Lists all individuals who have been deemed to have completed a nurse aide training and competency evaluation program;
- Lists all individuals for whom the requirement to complete a nurse aide competency evaluation program has been waived by the State;
- Lists all nurse aides who have been found by the State to have abused or neglected a resident or misappropriated resident property;
- Removes entries for all individuals who have performed no nursing or nursing-related services for monetary compensation for a period of 24 consecutive months except those individuals who have been found to have abused or neglected residents or misappropriated resident property;
- Discloses the date of eligibility for placement on the registry and any information pertaining to a finding of resident abuse or neglect or misappropriation of resident property to everyone requesting information about an individual on the registry. (You may disclose any additional information you deem necessary.);
- Provides individuals on the registry with all information in the registry on them when findings of resident abuse or neglect or misappropriation of resident property are made or upon request;
- Permits all individuals on the registry sufficient opportunity to correct any misstatements or inaccuracies contained in the registry;
- Is sufficiently accessible to meet the needs of the public and health care providers;
- Provides requested information promptly; and
- Does not impose any charges related to registration on individuals listed in the registry.

The nurse aide registry may include information on home health aides who have successfully completed a home health aide training and competency evaluation program approved by the State if home health aides are differentiated from nurse aides.

B. Registry Information.-- The following items must be maintained and retrievable from the nurse aide registry for each individual who has completed a nurse aide training and competency evaluation program or competency evaluation program approved by the State, who has been deemed to have completed a nurse aide training and competency evaluation program, or for whom the State has waived the competency evaluation requirement:

- o The individual's full name.
- o Information necessary to identify the individual.
- o The date the individual became eligible for placement in the registry.
- o Any finding by you of resident abuse or neglect or misappropriation of resident property by an individual documenting:
  - -- Your investigation, including the nature of the allegation andthe evidence that led you to conclude that the allegation was valid;
  - -- The date of the hearing (if the individual chose to have one) and its outcome; and
  - -- A statement disputing the allegation, if the individual chose to make one.

Findings of resident abuse or neglect or misappropriation of resident property against a nurse aide must be included in the registry within 10 working days and must remain in the registry permanently, unless the finding was made in error, the individual was found not guilty in a court of law, or the State is notified of the individual's death.

C. Responsibility for the Nurse Aide Registry.-- The State may contract the daily operation and maintenance of the registry to a non State entity; however, the State must maintain overall accountability for operation of the registry and compliance with regulations, and only the State survey agency is permitted to place findings of resident abuse or neglect of misappropriation of resident property on the registry.

4470. SPECIFICATION OF RESIDENT ASSESSMENT INSTRUMENTS FOR USE IN LONG TERM CARE FACILITIES

4470.1 Statutory Requirements--Sections 1819(b)(3), 1819(e)(5), 1819(f)(6)(B), 1919(b)(3), 1919(e)(5), and 1919(f)(6)(B) of the Act specify assessment requirements for skilled nursing facilities (SNFs) for Medicare and nursing facilities (NFs) for Medicaid, which provide nursing, medical, and rehabilitative care to Medicare and/or Medicaid beneficiaries. These provisions require facilities to conduct comprehensive, accurate, standardized, and reproducible assessments of each resident's functional capacity using a resident assessment instrument that has been specified by the State. In addition, all resident assessment instruments must include the minimum data set of core elements, common definitions and utilization guidelines specified by HCFA. (See §4470.2.)

These provisions place specific responsibilities on the Department, the State, and providers. HCFA is responsible for specifying the minimum data set, common definitions and utilization guidelines and for designating one or more resident assessment instruments for use by the States. The States are responsible for specifying the resident assessment instrument for use by facilities in the State. The State may use a resident assessment instrument designated by HCFA or specify its own instrument provided that it includes the minimum data set and has been approved by HCFA. The providers are responsible for using the specific assessment instrument that has been specified by the State.

4470.2 Definitions

- Minimum Data Set (MDS)--A minimum set of screening and assessment elements, including common definitions and coding categories, needed to comprehensively assess an individual nursing home resident. The items in the MDS standardize communication about resident problems and conditions within facilities, between facilities, and between facilities and outside agencies.

- Common Definitions--Standardized explanations of each element specified in the MDS.

- Coding Categories--Levels of measurement for each element included in the MDS.

- Triggers--Levels of measurement (coding categories) of MDS elements that identify residents who may require further evaluation using resident assessment protocols designated by the State.

o Resident Assessment Protocols (RAPs)--Structured frameworks for organizing MDS elements, and additional clinically relevant information about an individual that contribute to care planning. (The State is not required to use the term "resident assessment protocol" in defining structured frameworks.)

o Resident Assessment Instrument--A standardized system comprised of the MDS and RAPs, including triggers, that result in a comprehensive, accurate, standardized, reproducible assessment of each long term care facility resident's functional capabilities.

o Utilization Guidelines--Instructions concerning when and how to use the resident assessment instrument.

4470.3 MDS and Resident Assessment Instrument Designated by HCFA.--HCFA is responsible for specifying the MDS, its common definitions and utilization guidelines, and for designating one or more resident assessment instruments. HCFA's proposed resident assessment instrument is specified in Appendix R of the State Operations Manual (SOM). Copies of Appendix R may be obtained by writing to:

Director, Division of Long Term Care Services
Office of Survey and Certification, HCFA
Meadows East Building - Area 2-D-2
6325 Security Boulevard
Baltimore, MD 21207
Attn: Nursing Home Branch

The resident assessment instrument is comprised of the utilization guidelines, the MDS of core elements and common definitions, and the RAPs. The utilization guidelines are specified in Appendix R, Part I; the core elements of the MDS and common definitions are specified in Part II; and the RAPs, triggers and instructions for use in Part III.

4470.4 Specification of a State Resident Assessment Instrument.--The State must specify a resident assessment instrument for use in the long term care facilities in your State participating under Medicare and/or Medicaid. You may either specify the resident assessment instrument designated by HCFA, which is comprised of utilization guidelines, the MDS with common definitions, and the 18 RAPs with triggers and a documentation format (see Appendix R) or you may specify an alternate instrument for use in your State. If you specify an alternate instrument, it must be approved by HCFA. To receive approval, an alternate instrument must contain:

o The Utilization Guidelines. See Appendix R, Part I of the SOM.

o The MDS. See Appendix R, Part II of the SOM. All data elements and corresponding coding categories specified in the MDS must be contained in the State's instrument. You may not alter the MDS definitions or the coding categories used with each MDS element. You are encouraged to maintain the elements within the section in which they appear on the MDS and maintain the order of the sections of the MDS. However, if adequately justified by supporting clinical or operational rationale and accompanied by a conversion table between the State's instrument and HCFA's MDS, you may request approval to:

- Reorder the major sections of the MDS. For example, Section E. -Physical Functioning and Structural Problems on the MDS may be moved to between Section B. -Cognitive Patterns and Section C. -Communication/Hearing Patterns and the sections relettered.

- Relocate an MDS element(s) from one section of the MDS to another as long as the change does not interfere with the element's effectiveness for assessment.

- Include data elements additional to those in the MDS that are needed to meet unique State operational needs. These additional items will only be reviewed by HCFA to assure there is no conflict with elements included in the MDS, i.e., HCFA will not evaluate the merits of your including those elements.

o RAPs. An alternate resident assessment instrument must include structured frameworks for organizing MDS elements and additionally relevant information about an individual that contributes to care planning. The State is not required to use the term RAP in an alternate instrument and a State's protocol.

A State developed alternate resident assessment instrument must provide frameworks for comprehensive assessment in the following care areas:

- Cognitive loss/dementia;

- Visual function;

- Communication;

- Activities of daily living functional potential;

- Rehabilitation potential (HCFA's instrument combines the Rehabilitation RAP with the ADLs RAP);

- Urinary incontinence and indwelling catheter;

- Psychosocial well-being (In the HCFA-designated instrument, in addition to a distinct psychosocial well-being protocol, there are three distinct RAPs that bear on psychosocial functioning: "mood", "behavior", and "delirium".);

- Activities;
- Falls;
- Nutritional status;
- Feeding tubes;
- Dehydration/fluid maintenance;
- Dental care;
- Pressure ulcers;
- Psychotropic drug use; and
- Physical restraints.

These care areas may be combined in different ways to create a RAP comparable to that designated by HCFA. For example, you may have a RAP that combines nutritional status and tube feeding or activities of daily living and rehabilitation potential. However, if you create alternative RAPS through combining care areas, you must provide a cross-walk chart from your RAPs to the above care areas.

Include in each RAP you develop assessment triggers, based on MDS elements or other information requirements, that screen which residents are subject to additional assessment.

If you select alternative triggers and/or information requirements for your RAI, you should provide supporting documentation for your decisions. Such documentation may take the form of citations from the literature, results of field testing, or the consensus of experts that you use to assist in designing these RAPs.

Specify a standardized approach that long term care facilities will use to document information derived from RAPs about the nature of problems, complications and risk factors, the need for referral to appropriate health professionals, and the reasons for deciding to proceed or not to proceed with care planning specific to the triggered problems. There must be provision for identification of the location of these assessment results so that they can be easily retrieved and for certification of completion accuracy. (See the RAP formats designated by HCFA in Appendix R, Part III.) Also, we advise you to encourage facilities to maintain the MDS data in computer readable form.

4470.5 Approval Process.--Inform HCFA by October 19, 1990, whether you intend to specify the resident assessment instrument designated by HCFA or request approval for your State instrument. When requesting approval for your State instrument, include a copy of the instrument and its instructions, and a short narrative specifying how the instrument conforms with the utilization guidelines, the MDS, and RAPs. Include conversion tables and the name, address, and phone number of your State contact. Please send all correspondence concerning this matter to:

Director, Division of Long Term Care Services
Office of Survey and Certification, HCFA
Meadows East Building - Area 2-D-2
6325 Security Boulevard
Baltimore, MD 21207
ATTN: Nursing Home Branch

HCFA will review your instrument to determine whether it is an acceptable alternative, and will communicate directly with State representatives to clarify information, if necessary. HCFA will make every effort to work with you to meet your needs for resident assessment information. After you receive HCFA's approval, notify the providers within your State by providing a copy of the State's specified instrument and the procedures for using the instrument. You must assure that facilities begin using the specified instrument within 90 days after notification from the State. You must facilitate implementation by providing the necessary technical direction and training to facilities.

4480. PERSONAL CARE SERVICES

A. General.--Effective November 11, 1997, HCFA published a final regulation in the Federal Register that removed personal care services from regulations at 42 CFR 440.170 and added a new section at 42 CFR 440.167, "Personal Care Services in a home or other location." The final rule specifies the revised requirements for Medicaid coverage of personal care services furnished in a home or other location as an optional benefit. This rule conforms to the Medicaid regulations and to the provisions of §13601(a)(5) of the Omnibus Budget Reconciliation Act (OBRA) of 1993, which added §1905(a)(24) to the Social Security Act to include payment for personal care services under the definition of medical assistance

Under §1905(a)(24) of the Act, States may elect, as an optional Medicaid benefit, personal care services furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility for persons with mental retardation (ICF/MR), or institution for mental disease. The statute specifies that personal care services must be: (1) authorized for an individual by a physician in a plan of treatment or in accordance with a service plan approved by the State; (2) provided by an individual who is qualified to provide such services and who is not a member of the individual's family; and (3) furnished in a home or other location.

B. Changes Made by Final Regulation.--Personal care services may now be furnished in any setting except inpatient hospitals, nursing facilities, intermediate care facilities for the mentally retarded, or institutions for mental disease. States choosing to provide personal care services may provide those services in the individual's home, and, if the State so chooses, in settings outside the home.

In addition, services are not required by Federal law to be provided under the supervision of a registered nurse nor does Federal law require that a physician prescribe the services in accordance with a plan of treatment. States are now permitted the option of allowing services to be otherwise authorized for the beneficiary in accordance with a service plan approved by the State.

C. Scope of Services.--Personal care services (also known as personal assistance services) covered under a State's program may include a range of human assistance provided to persons with disabilities and chronic conditions of all ages which enables them to accomplish tasks that they would normally do for themselves if they did not have a disability. Assistance may be in the form of hands-on assistance (actually performing a personal care task for a person) or cuing so that the person performs the task by him/her self. Such assistance most often relates to performance of ADLs and IADLs. ADLs include eating, bathing, dressing, toileting, transferring, and maintaining continence. IADLs capture more complex life activities and include personal hygiene, light housework, laundry, meal preparation, transportation, grocery shopping, using the telephone, medication management, and money management. Personal care services can be provided on a continuing basis or on episodic occasions. Skilled services that may be performed only by a health professional are not considered personal care services.

1. Cognitive Impairments.--An individual may be physically capable of performing ADLs and IADLs but may have limitations in performing these activities because of a cognitive impairment. Personal care services may be required because a cognitive impairment prevents an individual from knowing when or how to carry out the task. For example, an individual may no

longer be able to dress without someone to cue him or her on how to do so. In such cases, personal assistance may include cuing along with supervision to ensure that the individual performs the task properly.

2. Consumer-Directed Services.--A State may employ a consumer-directed service delivery model to provide personal care services under the personal care optional benefit to individuals in need of personal assistance who are not cognitively impaired and have the ability and desire to manage their own providers. In such cases, the Medicaid beneficiary may hire their own provider, train the provider according to their personal preferences, supervise and direct the provision of the personal care services and, if necessary, fire the provider. The State Medicaid Agency maintains responsibility for ensuring the provider meets State provider qualifications (see E below) and for monitoring service delivery.

D. Definition of Family Member.--Personal care services may not be furnished by a member of the beneficiary's family. Under the new final rule, family members are defined to be "legally responsible relatives." Thus, spouses of recipients and parents of minor recipients (including stepparents who are legally responsible for minor children) are included in the definition of family member. This definition necessarily will vary based on the responsibilities imposed under State law or under custody or guardianship arrangements. Thus, a State could restrict the family members who may qualify as providers by extending the scope of legal responsibility to furnish medical support.

E. Providers.--States must develop provider qualifications for providers of personal care services and establish mechanisms for monitoring the quality of the service. Services such as those delegated by nurses or physicians to personal care attendants may be provided so long as the delegation is in keeping with State law or regulation and the services fit within the personal care services benefit covered under a State's plan. Services such as assistance with taking medications would be allowed if they are permissible in States' Nurse Practice Acts, although States need to ensure the personal care assistant is properly trained to provide medication administration and/or management.

States may wish to employ several methods to ensure that recipients are receiving high quality personal care services. For example, States may opt to a criminal background check or screen personal care attendants before they are employed. States can also establish basic minimal requirements related to age, health status, and/or education and allow the recipient to be the judge of the provider's competency through an initial screening. States can provide training to personal care providers. States also may require agency providers to train their employees. States can also utilize case managers to monitor the competency of personal care providers. State level oversight of overall program compliance, standards, case level oversight, attendant training and screening, and recipient complaint and grievance mechanisms are ways in which States can monitor the quality of their personal care programs. In this way, States can best address the needs of their target populations and develop unique provider qualifications and quality assurance mechanisms.

4560. SKILLED NURSING FACILITY (SNF) AND INTERMEDIATE CARE FACILITY (ICF) SERVICES PROVIDED BY SWING BED HOSPITALS

A. Background.--Pursuant to §1913 of the Social Security Act, you have had the option, since July 20, 1982, of amending your State plans to cover SNF-and ICF-type services when provided by certain hospitals. This option was enacted, for both Medicare and Medicaid, because of the shortage of long term care beds in rural areas.

The Medicaid provision allows you to exercise this option with those hospitals which have "swing bed" approvals under Medicare. Under those approvals, the hospitals can "swing" their beds between acute and long term care levels of care, on an as needed basis but, to do so, the hospital must meet the following requirements:

- Be located in a rural area (i.e., located outside of an "urbanized area," as defined by the Census Bureau, and based on the most recent census) and have fewer than 100 beds (excluding beds for newborns and intensive care type units);
- Have a hospital Medicare provider agreement;
- Be granted any necessary certificate of need;
- Be substantially in compliance with the SNF conditions of participation for patient rights, 42 CFR 405.1121(k)(2), (3), (4), (7), (8), (10), (11), (13) and (14); specialized rehabilitative services, 42 CFR 405.1126(a),(b) and (c); dental services, 42 CFR 405.1129; social services, 42 CFR 405.1130; patient activities, 42 CFR 405.1131; and discharge planning, 42 CFR 405.1137(h); (most other SNF conditions would be largely met by virtue of the facility 's compliance with comparable hospital conditions);
- Not have in effect a 24-hour nursing waiver granted under 42 CFR 405.1910(c); and
- Not have had a swing bed approval terminated within the 2 years previous to application for swing bed participation.

However, the Department may grant a swing bed approval, on a demonstration basis, with hospitals meeting all of the statutory requirements except bed size and geographic location.

Under §4005(b)(2) of the Omnibus Budget Reconciliation Act of 1987, effective for swing-bed agreements entered into after March 31, 1988, hospitals with more than 49 beds (but less than 100 beds) are subject to the following:

o If there is an available SNF bed in the geographic region, the extended care patient must be transferred within 5 days of the availability date (excluding weekends and holidays) unless the patient's physician certifies, within that 5-day period, that transfer of that patient to that facility is not medically appropriate on the availability date. In order to do this, hospitals need to identify all SNFs in their geographic region and enter into agreements with them for the transfer of extended care patients under which SNFs are to notify the hospitals of the availability of beds and the dates these beds will be available for extended care patients; and

o The 5 week day transfer requirement and the 15 percent payment limitation do not apply for Medicaid reimbursement purposes.

Hospitals having fewer than 50 beds and rural hospitals which entered into agreements before March 31, 1988 (i.e., those which were licensed for more than 49 beds but who were operating as a 50 or less bed facility) are not subject to the 5 week day transfer requirement or the payment limitation for extended care days. (See §2230.7 of the Provider Reimbursement Manual for the explanation of the payment limitation.)

"Geographic region" is an area which includes the SNFs with which a hospital has traditionally arranged transfers and all other SNFs within the same proximity to the hospital. In the case of a hospital without existing transfer practices upon which to base a determination, the geographic region is an area which includes all the SNFs within 50 miles of the hospital unless the hospital can demonstrate that the SNFs are inaccessible to its patients. In the event of a dispute as to whether an SNF is within this region or the SNF is inaccessible to hospital patients, the HCFA regional office shall make a determination.

B. Limitations and Payment.--If you choose to include in your plan coverage of SNF-or ICF-type services provided by swing bed hospitals, those services will be treated the same as SNF services furnished in a SNF and ICF services furnished in an ICF. Generally, Federal or State requirements applicable to SNF or ICF services would be equally applicable to swing bed long term care services, as appropriate (i.e., SNF requirements would apply to SNF-type services provided in swing beds and ICF requirements would apply to ICF-type services provided in swing beds).

Also, payment for long term care swing bed services under Medicaid are to be reimbursed at SNF or ICF rates, as appropriate. See 42 CFR 447.280.

4570. AMBULATORY SURGICAL CENTER SERVICES.

A. Background.--Ambulatory surgical center (ASC) services are currently coverable as clinic services under regulations at 42 CFR 440.90. They may also be covered under section 1905(a)(18) of the Social Security Act as ". . . any other medical care, and any other type of remedial care recognized under State law, specified by the Secretary."

B. Limitations and Payment.--ASC services provided under this benefit must meet the following requirements:

1. They must be provided by a distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization;

2. They must be furnished to outpatients;

3. They must be furnished by a facility that meets the requirements in sections 42 CFR 416.25-416.49; and,

4. They must be recognized under State law.

4580. PHLEBOTOMY AND CASE MANAGEMENT SERVICES ASSOCIATED WITH THE DRUG CLOZARIL

A. Background.--Clozaril was approved by the Food and Drug Administration in 1989, subject to the requirement that it would be provided only to patients who have weekly white blood cell counts. From February 1990 until June 1991, Sandoz Pharmaceuticals marketed Clozaril with an exclusive distribution system known as the Clozaril Patient Management System (CPMS).

From the perspective of the Medicaid benefit package, HCFA views Clozaril plus the associated services in three pieces: (1) the drug itself; (2) the laboratory tests; and (3) related services consisting of phlebotomy and case management type services to achieve the necessary monitoring. States are required to cover Clozaril, if they cover prescribed drugs under their State plans. In addition, States must provide the required laboratory services to categorically needy individuals. States are not necessarily required to cover the phlebotomy and case management types of services, depending upon whether they are components of mandatory or optional services listed in §1905(a) of the Act. If States cover these services, they may provide the phlebotomy and case management services either separately or can bundle the two services.

If your State chooses to cover case management services separately (unbundled), you can use either targeted case management or administrative case management, as a function necessary for the proper and efficient operation of the Medicaid State plan, as provided in §1903(a) of the Act. Case management may also be a component of other services listed in §1905(a) of the Act, such as physician or clinic services. If your State chooses to cover phlebotomy as a separate (unbundled) service, you can cover it as part of another service listed in §1905(a) of the Act, such as physician, home health or laboratory services. If States do not cover phlebotomy and case management services, the individual must provide for these services in order to receive Clozaril.

Section 1905(a)(22) of the Act defines medical assistance to include, among other things, ". . . any other remedial care recognized under State law, specified by the Secretary." Accordingly, HCFA has determined that the phlebotomy and case management services may be provided as a bundle of component services which an individual must receive in order to receive the drug Clozaril under §1905(a)(22) of the Act.

B. Limitations and Payment.--You may cover the drug Clozaril and the associated services in the following manner:

- The drug must be included under the coverage of prescription drugs described in §1927 of the Act and in 42 CFR 440.120 and reimbursement in accordance with 42 CFR 447, Subpart D;

- The laboratory services, i.e., the white blood cell test must be covered under the laboratory services benefit and performed in accordance with 42 CFR 440.30;

- The remaining services, consisting of phlebotomy and case management type services may be covered as a bundle under other remedial care under the authority of §1905(a)(22) of the Act. Payment rates may be established in accordance with 42 CFR Part 447, Subpart D. Otherwise, case management may be covered separately (unbundled) as a separate service under §1905(a)(19) of the Act or as part of another covered service. Phlebotomy services may be covered separately (unbundled) as part of another service category; and

- The services must be recognized under State law.

4600. USAGE OF CERTIFICATION & TRANSMITTAL, HCFA-1539

A. Approval of Medicaid-Only Facilities.--When the State survey agency (SA) approves or reapproves an ICF or a SNF which participates only in Medicaid or which has a distinct part which participates only in Medicaid, the SA sends you both a yellow copy and a blue copy of the Certification & Transmittal, HCFA-1539. In these cases the HCFA-1539 provides a record of the SA's official determination approving the facility for participation. If you issue a new provider agreement or issue a renewal provider agreement to the facility (see §§4602 and 4602.1), complete items 19-31 of the form, sign the blue copy in the "Determination Approved" block at the bottom, and send the blue copy to the HCFA-RO. Keep the yellow copy.

If you decline to enter into an agreement with a SNF or ICF for good cause even though the SA has issued a determination of approval (see §4602), check box 2 in item 19 of the HCFA-1539 and give your reasons in item 30, "Remarks." Sign the blue copy and send it to the HCFA-RO. Keep the yellow copy.

B. Approval of Medicare-Only and Medicare/Medicaid Institutions.--In all certification approvals other than A, above, the SA sends the HCFA-1539 to the HCFA-RO as a record of its certification findings. The HCFA-RO uses it in making the determination whether to approve the institution and, in most cases, to enter into a provider agreement. In these cases, the SA sends you only the blue copy of the HCFA-1539. If a class of institution is subject to Medicare certification, you cannot enter into a provider agreement with such institution until it is approved for participation by HCFA. The HCFA-1539 is not a notice of approval in these cases. Wait to receive a copy of the HCFA notice of approval before issuing a Medicaid provider agreement.

C. Partial Approvals.--Laboratories and certain other institutions are often approved only for certain services that they perform. Medicaid provider agreements and payments must be limited accordingly. Modifications of coverage may occur quite frequently with laboratory tests, therefore keep track of the coverage change notices which the HCFA-1539s provide. However, as in B, above, wait to receive a copy of the HCFA determination notice of approval before taking any action. Provider agreements if issued to these classes of institutions are to be so worded that they do not require reissuance or modification each time the scope of approved services is modified.

D. Adverse Actions.--Be alert to the receipt of any HCFA-1539s indicating that an institution is no longer approvable, as well as to other notices from HCFA which indicate that a provider is being sanctioned on any grounds. HCFA may terminate participation or, in a Medicare SNF, HCFA may impose an alternative ban on payment for new admissions for eleven months. HCFA may take other adverse actions on grounds of fraud, program abuse, failure to comply with financial terms of the Medicare provider agreement, or utilization practices. Generally, Medicaid sanctions follow suit. See §4650ff for instructions on adverse processes.

In Medicaid-only long-term care facilities, if the HCFA-1539 shows that requirements are not met, promptly undertake the initiative to impose the sanction. However, you may disagree with the SA recommendation whether or not to deny payments for new admissions in lieu of immediate termination. If the SA recommended a denial of payments but you decide to terminate, enter a 2 in block 19 of the HCFA-1539, and explain your decision in Item 30. If the SA recommended termination and you decide to use the denial of payments, enter a 1 in block 19 and explain your decision in Item 30. Circle Item 30 in red ink on the blue copy and notify the SA of these changes so the SA can correct its revisit schedule.

4601. USAGE OF THE STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION, HCFA-2567

A. How the HCFA-2567 is Prepared.--The HCFA-2567 is a two-column, five-copy form. The left column is used to list deficiencies found in a SA survey. The right column is for the institution to respond by explaining how and when it will correct each deficiency.

When the SA surveys an institution, it usually issues a written list of deficiency findings by completing the left hand column of a HCFA-2567, citing each quality standard in question. It may omit the HCFA-2567 in some cases when, because the deficiencies present an immediate hazard to the health and safety of the patients or residents, the surveyor intends to recommend swift termination regardless of the possibility of subsequent correction. In terminations, the deficiencies are publicized in other ways. Most SAs even complete the HCFA-2567 to record "no deficiencies found," for reporting purposes. Sometimes the SA performs follow-up surveys to ascertain whether provider deficiencies have been corrected, and in those cases, it reports the fully corrected deficiencies on a Post-Certification Revisit Report, HCFA-2567B.

The usual practice when an institution is in compliance but has correctable deficiencies is to cite the deficiencies verbally at the end of the survey, and send a typed, reviewed Statement of Deficiencies by mail within 10 days. The institution generally has 10 days in which to return the form with the right hand column, Plan of Correction, completed with target dates for each correction. (Of course, the institution can make any response it chooses, such as denying that the deficiencies exist.) The nature of the response can influence the adjudicative conclusion whether the institution is complying with the standards or not. The SA includes copies of the HCFA-2567 in the certification materials sent either to you or to the HCFA-RO.

B. Processing HCFA-2567 for ICFs and Medicaid-Only SNFs.--Pursuant to section 1902(a)(36) of the Act and 42 CFR 431.115, you must:

- Provide in the State Plan that deficiency information will be disclosed in accordance with the regulation (along with ownership and contract information disclosable in accordance with 42 CFR 455.104);

- Have a procedure for disclosing the survey findings;

- Require the SA to:

  - Make the statements of deficiencies available to the public assistance office and Social Security office serving the area where the provider is located;

  - Submit a plan to HCFA for making the findings available to other public assistance agencies in locations where it would be helpful to users of the health service; and

  - Retain the statements and make them available to the public on request immediately upon approving or reapproving the facility and no later than 90 days after each survey.

When you send the certification materials forward to the HCFA-RO after taking your case actions (including following your disclosure procedure), include a copy of the HCFA-2567.

C. All Other HCFA-2567s.--You receive a copy of each HCFA-2567 (and each follow-up HCFA-2567B) after it has been cleared and disseminated by the HCFA-RO for public disclosure. Yours is an informational copy requiring no action. You may disclose its contents to anyone at any time.

4602. PROVIDER AGREEMENTS

A. Medicaid Provider Agreements.--Section 1902(a)(27) of the Act requires a system of formal agreements with every person or institution providing health services to Medicaid patients. Such persons or institutions must agree to furnish:

- Records necessary to fully disclose the extent of the services provided to individuals; and
- The State Medicaid agency or the Secretary of HHS with information requested regarding any payments claimed for providing these services.

42 CFR Part 442 introduces the term, "provider agreements" in this connection. The context makes clear in that Part 442, "provider" means SNF and ICF agreements. In Medicare, provider means a party that cares for the patient awaiting, receiving or recuperating from therapy given by an intervening practitioner, specifically, a hospital, hospice, home health agency, skilled nursing facility, or comprehensive outpatient rehabilitation facility. Part 442 extends the term provider to cover ICFs as well. (A HMO is not a provider; under Part 434 a HMO is a contractor.) You need not include in your definition other institutions which are certified for Medicare, such as independent laboratories and physical therapists, if Medicare defines them as "suppliers" rather than "providers." Your definition must be given in your State Plan, and should be included in any pertinent State regulations.

You may enter into a provider agreement with a SNF or ICF which has been approved by the SA, but you may refuse to enter into one, or you may cancel one, if you have adequate documentation showing good cause. What may constitute good cause is not particularized in the regulation, but should be specified in your State Plan and in any pertinent State regulations. For example, in an area where there is over-bedding in SNFs or ICFs, you may decide not to enter into a provider agreement.

B. Invalidation of Medicaid Provider Agreements by HCFA.--A provider agreement which you enter into may be invalidated by HCFA even if the SA certified the provider, if:

- Improper procedures were used to effect the approval and/or the agreement, or
- Any procedural State plan requirement was violated, or
- The facility is found by HCFA to be actually not in compliance with standards.
- The facility is not in compliance with Federal civil rights requirements.

In the first two instances, the agreement is considered invalid for FFP purposes from the beginning. FFP is disallowed for any payments made for care in the affected facility, and the State's only available appeal is through the HCFA grant disallowance procedures. In the third instance, the facility's participation is terminated prospectively, and the facility can appeal HCFA's overruling of the State action through HCFA's provider appellate procedures.

C. "Coterminous" Effective Dates of Provider Agreements.--If you enter into a provider agreement with a provider that participates in Medicare, the beginning and ending dates of the agreement must be the same as the Medicare agreement. Nonrenewal, cancellation, termination and payment sanction dates must also be the same as for Medicare.

The agreement must be effective on:

- The date the onsite survey is completed;
- The day following the expiration of a current agreement;
- The date the institution meets all requirements, or the date it submits an acceptable plan of correction, whichever is later.

4602.1 Terms of Time-Limited Provider Agreements With SNFs and ICFs.--Time-limited agreements are employed in long term care provider cases. The scheduled expiration of the agreement governs the length of time the certification is valid. Establish the length of the agreement based on the period of certification established by the SA. The length of the agreement may not exceed the certification period recommended by the SA; however, you may establish a shorter certification period when you deem it appropriate.

A. Full 12 Months.--Where there are no standards out of compliance, you may issue an unconditional agreement of 12 full calendar months.

B. Conditional 12 Month Agreement Subject to an Automatic Cancellation Clause.--Where a SNF or ICF is in compliance with the Conditions of Participation (standards for ICFs) but has deficiencies which must be corrected, you may execute a conditional agreement up to 12 full calendar months, subject to an automatic cancellation clause, i.e., 60 days after the projected correction date. Unless the corrections are completed as promised or there is substantial progress in carrying out the Plan of Correction, cancel the agreement.

This type of certification period is most appropriate where, despite the deficiencies, the facility is able to provide an adequate level of patient care, has responded with an acceptable Plan of Correction, and, by its past performance in correcting deficiencies, can reasonably be expected to make the necessary improvements.

C. Period of Certification Which Expires 60 Days After Plan of Correction.--Where a SNF has deficiencies in one or more standards, you may establish an expiration date two full months after the date specified for complete implementation of the Plan of Correction. The SA will resurvey after the implementation date. Cancel the provider agreement at the expiration date unless deficiencies have been corrected by the survey date.

D. Extension of the Agreement.--Extend the term of an expiring agreement one time only, for a period of two full calendar months if:

- The SA notifies you in writing before the original expiration date that the extension will not jeopardize patients' health and safety; and
- The extension is needed either to prevent substantial harm to the facility, to prevent hardship to the patients, or because it cannot be determined before expiration whether the facility has complied.

4603 READMISSION TO THE MEDICARE OR MEDICAID PROGRAM AFTER TERMINATION

A. Readmission of Medicaid-only SNF after Medicare Termination.--Before readmitting a SNF that has been terminated by Medicare, determine that the facility has provided to the SA reasonable assurance that conditions that caused termination will not recur. (When HCFA terminates a Medicaid-only facility pursuant to section 1910(c) of the Act, HCFA makes the reasonable assurance determination.)

The reasonable assurance period must be satisfied before you may issue an agreement to that facility and qualify for FFP. Your failure to require reasonable assurance is a basis for the RO disallowing FFP for the services furnished by that facility (42 CFR 442.30).

B. Readmission Criteria.--After the involuntary termination, cancellation, or nonrenewal of its agreement, the SNF cannot again participate in the Medicare or Medicaid program unless:

- The reasons for the termination, cancellation, or nonrenewal no longer exist;
- There is reasonable assurance that they will not recur; and
- All statutory and regulatory requirements are fulfilled.

C. Reasonable Assurance Concept.--Generally, the facility should be required to operate for a certain period of time without recurrence of the deficiencies which were the basis for the termination. Participation can only resume following that period. If corrections were made before making a new request for participation, the period of compliance before the request is counted as part of the period.

The HCFA-RO makes the determination whether or not the facility is eligible for readmission, for Medicare or Medicare/Medicaid facilities. You make the determination concerning readmission as a Medicaid-only SNF if the SNF had been terminated by HCFA as a Medicare/Medicaid facility.

To determine the reasonable assurance period, evaluate the following considerations:

l. Provider's Compliance History.--When the provider previously participated was compliance maintained historically? Were plans of correction implemented on time? Does the provider have a history of making good faith efforts to correct deficiencies and to maintain compliance? Does the provider have a record as being cited time after time for essentially the same problems? Was adverse action initiated against the provider but not put into effect?

2. The Facility's Compliance History.--Is the facility located in an area which is underserved by needed health professionals? Does the applicant's pay scale or the facility's location deter the hiring and retention of staff? Does the facility have inherent problems which are likely to cause the recurrence of significant deficiencies?

3. Correction of Deficiencies Which Constituted the Basis for Termination.--Have all deficiencies been corrected? Are corrective actions such that compliance is likely to continue?

The SA should conduct onsite visits during the reasonable assurance period to confirm provider compliance.

Examples using the above criteria to establish a reasonable waiting period for readmission follow:

Example A - The Happy Hill Convalescent Home was terminated on September 15, 1984. The facility was cited for several life safety code (LSC) violations: primarily, the absence of sprinklers in hazardous areas and smoke barriers in patient areas. The owner argued that corrective action was too expensive. On October 1, 1984, the facility was purchased by John Swift. Mr. Swift owns several SNFs in the State and is known to be a reputable provider. All of Mr. Swift's other facilities meet the LSC.

Reasonable Assurance - You determine that Mr. Swift may participate when the LSC deficiencies have been corrected and all other conditions are met.

Example B - Pleasant Plains Nursing Home was terminated on September 20, 1984. The facility corrected those deficiencies which led to termination and requested readmission on October 15, 1984. You review the provider's history of compliance and find that historically the facility had met substantially all program requirements. Documentation reveals that the

facility was the subject of uncontrollable staffing shortages which led to the deterioration of care and services and noncompliance with the Conditions. Current information affirms that the staffing problems have been resolved.

Reasonable Assurance - You established 30 days from October 15, 1984, as reasonable based on the facility's good compliance history and the resolution of the problems that led to termination.

Example C - Green Acres Nursing Home was terminated on November/1,/1984. The facility was cited as not meeting several Conditions of Participation. The facility alleged to have corrected all deficiencies on December 1, 1984, and requested immediate readmission. You reviewed the provider's compliance history and noted that one or more Conditions had been cited in each of the previous three surveys, but the facility usually managed to achieve compliance just before termination. Also the provider had been cited repeatedly for the same deficiencies, meaning that the provider was either unable or unwilling to maintain compliance.

Reasonable Assurance - You establish 60 days from December 1, 1984 as reasonable based on the facility's history of not maintaining compliance.

Example D - Fox Chase Nursing Home was terminated on December 21, 1984, for its failure to maintain required staffing levels in nursing, dietary, and medical records. The facility alleged on January 2, 1985, that it hired the necessary staff and requested readmission. Upon review, you find that the facility is located in a remote, underserved rural area. Periodically, the facility has failed to maintain staff since participation began in 1978.

Reasonable Assurance - You establish 90 days from January 2 as reasonable on the grounds that the location of the facility has militated against staff retention, and that 3 months of continued compliance would evidence the facility's ability to retain qualified health professionals.

Example E - The ABC Convalescent Home was terminated on September 15, 1984. Ms. Johnson, the owner of ABC, had repeatedly been cited as not meeting several of the Conditions, but had, until this most recent survey, achieved compliance before termination action would be completed. Ms. Johnson, on October 1, 1984, alleged compliance.

Reasonable Assurance - You establish a 120 day waiting period based on the facility's repeated failure to meet the Conditions of Participation necessary to ensure the health and safety of patients.

Example F - The ABC Convalescent Home was readmitted following a 60 day reasonable assurance period and on the next survey cycle is found not to meet one or more Conditions, and is terminated once more. The provider corrects the deficiencies and requests readmission.

Reasonable Assurance - You establish a 120 day period based on prior termination and failure to maintain compliance following a 2 month reasonable assurance period.

D. Effective Date of Provider Agreement.--The agreement cannot be effective earlier than the date on which compliance is documented via the SA's onsite visits to the institution, and the reasonable assurance provision, if applicable, is met. The reasonable assurance provision only applies to SNFs that were previously a Medicare/Medicaid provider whose agreement was terminated by HCFA.

The HCFA RO monitors State reasonable assurance determinations, particularly if they conflict with the Medicare determination. If HCFA determines that the SA failed to require reasonable assurance from a facility, FFP is deferred until the RO verifies reasonable assurance. If reasonable assurance is not verified, HCFA disallows FFP for that facility. Also, be particularly careful if a SNF is terminated by HCFA under look-behind authority. (See §4651B.) In such cases, do not issue an agreement until HCFA agrees that reasonable assurance has been provided.

4604. AUTHORITY TO GRANT LIFE SAFETY CODE WAIVERS FOR MEDICAID ONLY NFs

When Medicaid NFs and Medicaid distinct part NFs request a waiver of Life Safety Code requirements in accordance with §1919(d)(2)(B)(i) of the Social Security Act, the SA forwards such requests to the HCFA RO for review and approval.

4650. TERMINATION - GENERAL

Termination procedures vary depending on whether or not an institution's deficiencies pose an immediate and serious threat to patient health and safety and depending on how Medicaid cases are affected by HCFA termination procedures. While you are not mandated to meet procedures not specified in the State plan requirements, your State plan should be evaluated against HCFA's requirements because the greater the deviation from operating procedures and general instructions that HCFA believes to be good practice, the greater the risk of FFP disallowances or compliance actions.

4651. BASIS FOR TERMINATING PROGRAM PARTICIPATION

A. Termination of Medicaid Participation.--Terminate a Medicaid agreement or deny payments for new admissions when the SA determines that the provider does not meet applicable program requirements. If a SNF participates concurrently in the Medicare and Medicaid programs and HCFA terminates Medicare participation, Medicaid participation must be coterminous.

B. Cancellation of Medicaid Agreement by the Secretary.--HCFA has authority under §1910(c)(2) of the Act to terminate the approval of a SNF or ICF to participate in the Medicaid program when HCFA determines that the facility fails to comply substantially with the Conditions of Participation, 42 CFR 405, Subpart K (SNFs), or with the standards contained in 42 CFR 442, Subparts D, E, F, or G (ICFs). In these instances the termination is prospective, occurring after the provider has had the opportunity for a formal hearing before an Administrative Law Judge, unless the Secretary determines there is jeopardy to patients' health or safety. If there is an immediate and serious threat to patients' health and safety, termination occurs within 5 days after notification by the RO with opportunity for a post-termination hearing.

This authority is in addition to another look-behind authority under 42 CFR 442.30. The latter provides that a provider agreement is considered invalid for purposes of providing FFP to the State, unless the State has followed proper procedures. e.g.. if you issued a provider agreement even though the SA had not certified the facility as being in compliance. In those instances, the agreement is considered void from its inception, and the State is not entitled to FFP for any of the bills related to the facility. The only appeal provided after this procedural kind of disallowance is through the grant award process.

C. Termination of Medicaid-Only Skilled Nursing and Intermediate Care Facilities.--Federal Medicaid regulations provide for terminations, nonrenewals, and cancellations, but do not fully describe the implementing procedures. Each State has developed procedures for terminating agreements with SNFs and ICFs when those facilities are not found to be in substantial compliance with program requirements. In a Medicaid-only noncompliance

situation, the SA determines that the facility is no longer approvable, prepares the necessary documents, and forwards the documentation to you for termination, nonrenewal or cancellation of the Medicaid agreement. Notify HCFA and the public of your action, and afford the facility notice and opportunity for a hearing.

4651.1 Lock-out of Approved Facility Because of Program Abuse.--Under 42 CFR 431.54(f), you may also "lock out" a SNF or ICF for a reasonable period of time if the facility has abused the Medicaid program. This may occur even though the SA has approved the facility. Criteria and procedures for "lock out" should be spelled out in your State Plan and in any pertinent State regulations.

4651.2 ICF Given Time to Recomply With State Licensure Requirement.--An ICF, including an ICF/MR, which meets all other standards but fails to meet requirements for State licensure which it formerly met, may continue to be approved by the SA. This occurs only for a period of time approved by the SA, and is contingent upon the facility taking positive steps during that time which will regain the level of compliance. Do not terminate such cases, but when you renew the agreement, include a cancellation clause for 60 days after the end of the time period allowed by the SA.

4651.3 Intermediate Sanctions Before Termination.--

A. Denial of Payment for New Admissions All Long-Term Care Facilities.--Before considering termination of a SNF or ICF, consider adjudicatively imposing a ban on payment for new admissions. This presupposes that the deficiencies present no immediate jeopardy to health and safety. Impose the ban for eleven months, though it is possible that changed circumstances could result in either lifting the ban or invoking termination before the eleven months have elapsed. After eleven months, either terminate or reapprove the facility, depending on its re-achieving compliance.

B. Correction/Reduction Plans ICFs/MR Only.--Section 9516 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (§1919 of the Act) provides you two additional options under which ICFs/MR can continue to participate. These options apply only when substantial deficiencies are found by HCFA in physical plant and staffing (or physical plant, staffing and minor deficiencies in other areas) that do not pose an immediate threat to clients' health and safety. You may either submit a reduction plan or a correction plan (See §3651.5). You may submit written plans either to make all necessary staff and physical plant corrections within 6 months of the approval date of the plan, or to reduce permanently the number of beds in certified units within 36 months of the approval date of the plan.

This process applies when, as a result of a direct Federal survey, there is a determination that an ICF/MR fails to comply substantially with physical plant and staffing standards contained in 42 CFR 442, Subpart G. ICFs/MR found to have substantial deficiencies in physical plant. staffing and other areas of care (e.g., active treatment, health care) are not eligible to use the options

available under §1919 of the Act, nor are facilities with no substantial physical plant or staffing deficiencies.

Substantial deficiencies, for purposes of this section, have not been defined by the Statute nor by the implementing regulations at 42 CFR 442.2. Therefore, determinations are made based on the RO judgment and assessment of their surveys' findings and recommendations, since it is not possible to define adequately and fairly the criteria given the wide diversity of facilities and clients served.

After receiving the list of deficiencies from the RO, you have the option to submit to the RO either of the following plans to remedy the deficiencies at the affected ICF/MR within the timeframes prescribed:

- Within 30 days, a plan to correct, or
- Within 60 days, a reduction plan.

If you intend to exercise either (or neither) of the options, refer to §1919 of the Act, and the implementing regulations at 42 CFR 442.114.

EXCEPTION: If, as a result of a public hearing, it becomes evident that the proposed reduction plan is not the appropriate option and you decide to submit a correction plan, the correction plan must be received by the RO within 20 days from the date of the public hearing.

Refusal to elect either option will result in termination of the ICF/MR's participation in the Medicaid program in accordance with §1910(c) of the Act.

Current regulations (§§442.105 through 442.111 and 442.113) are not related to the implementation of §1919 of the Act, because they regulate only the actions of the State survey agencies and not those of the Secretary that are authorized by §1919.

1. Correction Plans for ICFs/MR - Specific Requirements: Submit to RO a letter stating you choose the correction plan option along with a completed HCFA-2567. Include a timetable for completing the necessary steps to correct the staff and physical plant deficiencies, and all other minor deficiencies, within 6 months of the approval date of the plan. Even though there must be substantial deficiencies in physical plant and staffing for §1919 to apply, the plan must include how the facility will correct all deficiencies within 6 months.

Written approval or disapproval will be forwarded to you within 30 days of receipt of a proposed correction plan. The RO may assist in the preparation of a plan prior to its submission.

Final Determination: The RO will not delay the process of making a final determination on submitted correction plans beyond the specified 30-day review period for correction plans. Because of the serious nature of the deficiencies that the regulations address, the RO will avoid delaying action to correct the deficiencies. If the RO questions any aspect of the submitted plan or your ability to fulfill the requirements of the plan, they wi11 try to resolve their concerns with you.

If the correction plan is found unacceptable, the RO will notify you of its disapproval and will terminate the ICF/MR's participation in accordance with 1910(c) of the Act. No further negotiation or discussion is possible.

At the conclusion of the time period specified in the plan of correction, the RO will make a compliance or noncompliance determination based on actual conditions at the facility. If a noncompliance determination is made, the ICF/MR's participation will be cancelled in accordance with 1910(c) of the Act.

The facility retains its appeal rights if termination action results from either of these situations.

2. Reduction Plans for ICFs/MR - Specific Requirements.--A number of requirements are imposed if you elect to implement a reduction plan rather than correct the deficiencies cited at the facility in question. This is to assure that any such plan is well conceived, that it has had the benefit of client, family, staff, and public input, and that the quality of life for both the clients remaining in the facility and those receiving community placements is adequately protected. While some flexibility is allowed in the allocation of capital and staff resources between institutional and community settings, fiscal concerns are not to compromise the accessibility or quality of care and services to Medicaid-eligible clients.

The RO will forward written approval or disapproval of the proposed plan to your agency within 60 days of receipt of a proposed reduction plan.

Contents of the Reduction Plan: The following information is necessary to assure that the requirements of the submitted reduction plans will be fulfilled. Provide the RO with these assurances that the reduction plan can be carried out by the State. If the RO is not satisfied with the assurances, it will ask for the additional information necessary to make a final determination.

- Experiences of individuals in the State's relevant home and community-based waivers, if any;

- Recidivism rates from existing community services;

- A comparison of the number of individuals identified as being in need of services with the number of clients currently placed or served in the community;

- The length of time individuals must "wait" for services;

- The types of services being provided i.e., case management, health services and how are client needs assessed;

- Description of the existing system for referrals, into the service system. (What are the entry rules and procedures and how do clients get into the system?);

- The State plan objectives as related to the development of community services, and how those objectives are achieved and monitored;

- Consultation/input from Developmental Disabilities (DD) Council, and Mental Retardation (MR) Program Directors in the State;

- The percentage of home and community services in the State that are accredited by national accrediting organizations;

- Where services are implemented not by the State but by local planning and/or funding authorities, discussion of the prevalence of local authorities and whether they cover the State or are designated to limited districts; discussion of their ability to deliver services;

- Records and information that will be maintained to support financial accountability, including:

  -- Documentation of existing programs and level of funding, and

  -- Projections for growth and how the growth will be funded to accommodate the clients being displaced by the reduction plan.

Assure that community residences in which affected clients are placed meet all applicable State licensure requirements and all applicable State and Federal certification requirements.

- Describe the assessment system that evaluates the quality of care provided in these settings;

- Describe the participation of outside groups such as State and local DD Councils, Community Advisory Councils, Protection and Advocacy agencies, and human rights committees in providing safeguards.

When describing the methods used to select clients and develop services to meet their needs, include the following information:

- A copy of the instrument used for selection;

o A copy of the evaluation instrument used to determine the effectiveness of meeting client needs and reevaluating such actions at regular intervals:

-- Description of how decisions are made for client selection and the process used to determine client needs, i.e., involves the interdisciplinary team, client, and family;

-- The criteria used for client selection including assessment of independent living skills, client strengths, presence of family, homogeneity of skills;

-- The availability of particular services needed generally, as well as specialized service and/or equipment needs, (i.e., physical therapy, community mental health, barrier-free homes).

o Copies of relevant home and community-based standards in which clients will be placed, if any;

o Description of the network/community services required and evidence of provisions through contracts, grants, etc.; and

These requirements may be met through the provision of services under a home and community-based services waiver granted pursuant to §1915(c) of the Act. However, such waivers and amendments to such waivers are separate and distinct from reduction plans approved under §1919 of the Act. Separate application is required for these waivers, and approval of one program does not imply or require approval of the other. (See §4440.)

The reduction plan must not impair the Medicaid eligibility of an affected client without his or her consent. A reduction plan must provide that affected clients. who are eligible for Medicaid while at the facility, shall at their (or their legal guardian's) option, be placed in another setting, or another part of the affected facility that is in full compliance with Federal Medicaid requirements and therefore allows them to retain their Medicaid eligibility. The Medicaid agency may not involuntarily place a client in a setting where he or she loses entitlement to Medicaid. If the client would have remained eligible for Medicaid had the State opted to eliminate the deficiencies in the affected facility, then the State may not, at any time, involuntarily place the client in a setting where he or she loses entitlement to Medicaid. The client may elect to be placed in a setting where he or she does not retain entitlement to Medicaid. Of course, if the client or the client's guardian, voluntarily chooses to move to a setting--for example, back home with his or her family--that causes the client's countable income or resources to exceed the State's eligibility standards, then the client's Medicaid eligibility would be subject to termination under the same terms and procedures as applicable to all Medicaid beneficiaries.

The plan must adequately--

- o Inform clients of the feasible placement alternatives; and
- o Explain how clients will maintain eligibility for medical assistance while placed in the other setting.
- o Provide that the ratio of qualified staff to clients at the affected facility (or part thereof) will be the higher of:
  - -- The ratio which the RO determines is necessary to assure the health and safety of the remaining clients, or
  - -- The ratio which was in effect at the time of the direct Federal survey.

Clients must still receive active treatment. Therefore, the facility must provide adequate staff to provide needed care and services in a safe and healthful environment.

A reduction plan must also provide for the protection of the interests of employees affected by the reduction plan, including:

- o Arrangements to preserve employee rights and benefits;
- o Training and retraining of such employees, where necessary;
- o Redeployment of such employees to community settings under the reduction plan; and
- o Making maximum efforts to guarantee the employment of such employees. (This requirement is not to be construed as guaranteeing the employment of any employee.)

Public Hearing Requirement for Reduction Plans: Notify the general community (including advocacy groups, the courts with which the ICF/MR is involved in litigation, if any, and other interested groups and agencies) of the public hearing on a proposed reduction plan through local media notices. Public notice must be made at least 10 days prior to the hearing date. Additionally, a written individual notice of your public hearing on a proposed reduction plan to clients or their parents, legal guardians and/or interested parties is required. Written individual notice is to include the nearest or most involved member of the affected clients, if any. The notice must include the exact date, time and location of the hearing, as well as the locations where the proposed plan is displayed. Notice to facility staff may be provided through established channels of communication within the ICF/MR. The ICF/MR may notify facility staff through routine written memoranda, posted notices in areas frequented by all staff or through other methods commonly used at the ICF/MR.

The plan must include minutes of the public hearing held at the affected facility with a summary of the issues discussed detailing the various points of view presented by those in attendance.

HCFA is permitted to approve 15 reduction plans per fiscal year, on a first come, first served basis without stipulations regarding the minimal costs that would be incurred to correct the deficiencies. All plans submitted thereafter must demonstrate to the satisfaction of the RO that at least $2,000,000 in State or local funds must be spent to remedy the substantial physical plant and staffing deficiencies found. Since the RO will not know which will be the 16th plan submitted, all reduction plans submitted are to include documentation of the costs involved to correct the substantial physical plant and staffing deficiencies (referred to in §442.116(e)(2)) using the HCFA-2567. Provide documentation from a certified architect or contractor of the projected costs and specific structural changes or renovations necessary to remedy the physical plant deficiencies and documentation of staff budget requests.

The date the RO receives the plan with all needed supporting information will be used to determine whether the plan qualifies for consideration within the first 15 approvals.

Final Determination: Because of the serious nature of the deficiencies that the regulations address, the RO will not delay making a final determination on submitted reduction plans beyond the specified 60-day period for reduction plans (allowing for the statutorily mandated 30 day public comment period). The RO will assist you in the preparation of a plan prior to its submission, if requested. If the RO questions any aspect of the submitted plan or your ability to fulfill the requirements of the plan, they will work with you to resolve their concerns.

Termination of an ICF/MR: Substantial failure to meet any of these reduction plan requirements subjects the State to one of two sanctions:

- Termination of the facility's provider agreement, or

- Disallowance of Federal Medicaid matching payments equal to 5% (five percent) of the cost of care for all eligible individuals in the facility for each month of noncompliance.

The RO has discretion as to which sanction to apply, but must apply one or the other. If, after any six-month period, the RO determines that a State failed to meet the reduction plan provisions §442.116, and determines the State has not made a good faith effort to meet those requirements, or if conditions worsen irrespective of "good faith efforts," the RO will initiate termination procedures. If the RO determines failure to comply with the requirements resulted despite the State's best efforts, the RO will apply a disallowance penalty of five-percent of the cost of care for all eligible individuals in the facility for each month that the requirements were not met. Good faith efforts apply only to the reduction plan. In the case of the correction plan, the RO will make a compliance or noncompliance determination based on actual conditions in the facility and not based on the "good faith efforts" of the provider.

4652. TERMINATION PROCEDURES--IMMEDIATE AND SERIOUS THREAT TO PATIENT HEALTH AND SAFETY

A. Substantial Noncompliance With Program Requirements Which Pose an Immediate and Serious Threat to Patient Health or Safety.--"Immediate and serious threat" is interpreted as a crisis situation in which the health and safety of patients is at risk. Generally, it is a deficient practice which indicates the operator's inability to furnish safe care and services. An immediate and serious threat to patient health or safety may exist in the presence of one or more of the following (or similar) situations. This list is not to be interpreted as all-inclusive, but rather as examples of what HCFA believes may constitute an immediate and serious threat. The surveyor is always expected to describe findings in sufficient detail to show the relative seriousness of the hazard.

o Widespread insect or rodent infestation indicative of food contamination or the possible spread of contagion.

o Failure to control infections as evidenced by the presence of facility acquired infections.

o Widespread patterns of patient abuse or poor patient care, including:

- Instances of malnutrition or dehydration that are unrelated to the patient's condition and are a result of poor patient care;

- A pattern of negligence by staff with the result that patients are often left lying in urine, feces or other waste;

- Use of physical or chemical restraints in excess of that which is ordered by a physician.

o Drug or pharmaceutical hazards that directly affect patient health and safety, such as:

- Widespread drug errors, mishandling of drugs or other patient related pharmacy problems;

- Failure to provide medications as prescribed;

- Failure to monitor drugs as evidenced by lack of ordered laboratory work, failure to take vital signs as indicated by drug regimen, and lack of other nursing monitoring practices;

- Gross mishandling of drugs such as leaving drug trays unattended and available to patients and visitors.

- Administration of drugs by unqualified staff; or

- Administration of experimental drugs without the informed consent of the patient (or responsible party).

B. Processing of Immediate and Serious Threat Terminations.--When an immediate and serious threat to patient health or safety is documented, all termination procedures are to be completed within 23 calendar days. HCFA believes this to be a reasonable amount of time either for termination or for correction of the deficiencies which constitute an immediate and serious threat. Both you and the SA should accelerate the termination process in cases involving an immediate and serious threat to patient health and safety.

If there is a credible allegation that the threat or deficiency has been corrected, at least one resurvey prior to termination should be conducted by the SA.

Do not use this procedure if there is a time-limited agreement that is subject to cancellation or nonrenewal within 23 days after the survey. In those cases, process the cancellation or nonrenewal as explained in §4654.

Medicaid agreements with facilities that concurrently participate in Medicare must be terminated on the same date the Medicare agreement is terminated (42 CFR 442.20).

4653. TERMINATION PROCEDURES--NONCOMPLIANCE LIMITS CAPACITY OF FACILITY TO FURNISH ADEQUATE LEVEL OR QUALITY OF CARE - NO IMMEDIATE AND SERIOUS THREAT TO HEALTH AND SAFETY

Failure to meet the intent of one or more Conditions is one cause for termination of program participation. If Medicare decides to terminate rather than impose a denial of payments for new admissions, the termination will take effect within 90 days following the date of survey, unless compliance is achieved before the effective date of termination. When Medicare terminates a dually participating SNF, terminate the Medicaid agreement on the same date.

With respect to long-term care facilities as explained in §4651.3 and §4654, termination is one option among other sanctions. If in a Medicaid-only case, you opt to terminate when there is not immediate jeopardy to health and safety, follow §4653.1 through §4655.

4653.1 Interruption of Termination Timetable

A. Credible Allegation of Compliance.--Have the SA conduct a revisit following receipt of any credible allegation of compliance from a facility. A credible allegation is one:

o Made by a facility with a history of having maintained a commitment to compliance, and taking corrective action if required,

- That is realistic in terms of the possibility of the corrective action having been accomplished between the exit conference and the date of the allegation, and

- That actually resolves the problems created by the deficiency.

Only actual restoration of compliance can rescind termination action.

B. Informal Hearings Do Not Interrupt the Timetable.--The process may not be postponed to accommodate informal hearings or meetings or to give the facility additional time to achieve compliance. Such discussion may, however, be conducted within the procedural time limits above, as you deem appropriate. This 90 day procedure provides adequate time for the provider to achieve compliance if your decision is to wait the full time allowed and if the well-being of patients is not jeopardized in the interim.

C. Acceleration of Timetable.--Switch from the 90-day procedures to the accelerated procedures at any point when:

- There is an immediate and serious threat to patient health and safety, or

- An acceptable and reasonable plan of correction is not submitted; i.e., the provider cannot achieve compliance within 90 days, or

- The provider has not shown good faith efforts to achieve and maintain compliance with all program requirements.

D. Termination Coinciding with Change of Ownership.--A change of ownership does not affect completion of a termination action. Do not postpone any required termination. Do not solicit a plan of correction from the new owner. Court appointed receivership is not a basis for cessation of the termination process. Following termination, the new owner may, however, request approval for participation as a new provider, subject to reasonable assurance provisions. (See §4603.)

E. Disagreement Over Deficiencies.--A provider that disagrees with any SA finding regarding a cited deficiency or an acceptable plan of correction should be advised to express its position on the plan of correction in statutory or regulatory terms, and to specify why the SA's citation is not correct. This information does not interrupt the termination process, but is publicly disclosable and will be included in the documentation considered during any subsequent adjudication or hearings.

4653.2 Termination Documentation.--If you have any reservations about the SA's recommendation to terminate a facility, request copies of the current Survey Report and copies of previous Survey Reports to insure that all items are properly completed.

4653.3 Completion and Forwarding of HCFA-462.--The Adverse Action Extract, HCFA-462, was developed to monitor SA and HCFA-RO adherence to termination processing time limits. The form is used whenever a facility is cited as not meeting one or more Conditions. For ICFs and Medicaid-only SNFs, complete a HCFA-462, when the deficiencies cited result in a certification of non-compliance unless actually corrected before certification. Information provided on the form is entered into the Medicare/Medicaid Automated Certification System (MMACS) and used to monitor any adverse action initiated against a Medicare or Medicaid provider, supplier or facility.

The HCFA-462 is initiated by the SA and copies forwarded to the HCFA-RO immediately following specific SA actions; i.e., survey, followup visits, certification of compliance. For Medicaid-only facilities the SA forwards it to you to complete the appropriate items (10, 12, 13 and 17), in Parts II and III of the form. After you complete it, send a copy to the HCFA-RO.

4654. NONRENEWAL OR CANCELLATION OF TIME LIMITED AGREEMENTS FOR LONG TERM CARE FACILITIES (MEDICARE AND MEDICAID)

A. General.--Time limited agreements (TLAs) of 12 months or less are required by regulations for SNFs and ICFs including ICFs/MR (but not for hospitals having "swing bed" agreements to provide long term care). Like any agreement, a TLA may be terminated. However, unlike other agreements, a TLA may also be nonrenewed or automatically cancelled. The decision to terminate instead of nonrenew or cancel depends on the timing of the onsite survey; i.e., how close in time the survey is to the expiration date or automatic cancellation date, and the seriousness of the deficiencies cited.

Nonrenewal and cancellation are preferred alternatives to termination if termination would be effective later than the time of projected renewal or automatic cancellation date.

B. Nonrenewal of Time Limited Agreements.--A nonrenewal is the decision not to renew a TLA following its expiration.

1. Situations Leading to Nonrenewal.--A facility does not qualify for renewal of its agreement if it has been determined, based on resurvey, that:

- The facility has violated the terms of its agreement or the provisions of title XIX, or applicable regulations; or
- The facility does not substantially meet one or more program requirements (e.g., Conditions of Participation for SNFs and standards for ICFs or ICFs/MR, or has an unacceptable plan of correction); or

- The facility continues to be substantively out of compliance with the same standard(s) (consistently maintains major deficiency) for SNFs, ICFs, or ICFs/MR that were found out of compliance during the last survey on which the current certification period was based. In other words, the deficiency persists through the term of its current agreement.

EXCEPTION: A new period of certification may be approved even though the same standard(s) was out of compliance at the time of resurvey if:

- The deficiencies did not substantially limit the facility's ability to furnish adequate care or adversely affect the health and safety of patients, and

- The facility can document that it achieved compliance during the term of the agreement, but for reasons beyond its control was again out of compliance prior to the expiration of the agreement.

2. Timing of Resurvey.--In nonrenewal cases, the facility must be given formal notice of your decision not to enter into a new agreement prior to the date of expiration of its existing agreement. Therefore, the recertification survey should be completed by the SA between 60 and 120 days in advance of the expiration of the term of the agreement. All nonrenewal procedures must be completed by the expiration date of the current agreement.

Process a termination in lieu of nonrenewal if the renewal date is more than:

- 90 days after finding noncompliance, or

- 23 days if you find there is an immediate and serious threat to patient health and safety.

3. Facility Does Not Want to Renew.--A participating facility may choose not to renew its agreement.

C. Cancellation of Time Limited Agreements

1. General.--The TLA must contain an automatic cancellation clause if uncorrected deficiencies existed at the time of the last survey. In this case, the SA will specify a date not later than the 60th day following the end of the time period specified for such corrections. This should be not later than the end of the ninth month of the agreement. The cancellation clause provides that if the corrections of deficiencies are not made by the date the SA has specified, or if substantial progress has not been achieved in accordance with an accepted plan of correction, the agreement will automatically terminate on that date. However, if substantial progress is made and an updated plan of correction accepted, the facility may continue to participate. The SA establishes a control on all cancellation clause agreements to ensure that a verification visit is performed as soon as possible after the last date specified in the facility's plan of correction.

The procedures implementing the cancellation clause are similar to those required for an involuntary termination. They require comparable development, supporting documentation, and internal clearance action.

However, the basis for invoking this clause may be limited to establishing that the facility has not made substantial progress in carrying out its plan of correction. Whenever a cancellation clause is "invoked", undertake termination action to remove the facility from participation status. All cancellation procedures must be completed by the cancellation date.

The SA will document and notify you if the verification visit establishes that the facility has made the necessary corrections, or has made significant improvement, justifying continuance of the agreement based on an updated plan of correction. To document correction or significant improvement, the SA will use one or both of the following forms:

- HCFA-2567B for deficiencies which have been corrected.
- Revised HCFA-2567 for deficiencies not corrected. The SA will prepare and forward the documentation to you with a HCFA-l539, noting their determination.

2. Substantial Progress in Correcting Deficiencies Where There is a Cancellation Clause.--"Substantial progress" means that corrections are well underway; that there is tangible and visible progress. For example, if the installation of a sprinkler system is required but the system is not yet operating, there should be evidence of progress at the time of the revisit, such as the installation of piping. If the only progress by the facility to date has been a loan application which is still pending, this would not constitute substantial progress sufficient to prevent invoking the cancellation clause. However, extenuating circumstances that are beyond the control of the facility can be considered in determining whether or not to continue the facility in the program.

If the verification visit establishes that the facility has made the necessary corrections, or has made significant improvement justifying continuance of the agreement based on an updated plan of correction, the SA completes the following forms:

- HCFA-2567B for deficiencies which have been corrected.
- HCFA-2567--Includes deficiencies not corrected from the previous HCFA-2567.

Notify the facility that based on the correction of all deficiencies or the revised plan of correction, the cancellation clause will not be invoked and the agreement will continue to its full term.

3. Facility Fails to Make Corrections or Substantial Progress.--Documentation for invoking the cancellation clause need not necessarily be as extensive as that for an involuntary termination. Survey efforts may be limited to the confirmation of the continued existence of the deficiencies. However, the documentation must be clear, convincing, and of the same high quality as that for an involuntary termination action.

4655. NOTICE OF TERMINATION

Notify the facility of its termination, cancellation or nonrenewal, and of its appeal rights in accordance with your State Plan requirements. Publish an advance public notice giving the effective date of and reasons for termination.

4656. ADDITIONAL COMMUNICATIONS WITH FACILITY

After the SA forwards the certification of noncompliance to you, document all further contacts with the facility. Unrecorded visits, surveys, or correctional allegations that were not reported before final termination action could cause embarrassment or even result in failure to sustain the termination action. Even after final termination action, any additional contacts may be pertinent to proper handling of the case.

4657. RELOCATING PATIENTS OR RESIDENTS DISPLACED BY TERMINATION OR CLOSURE

A. General.--There are instances when patients or residents in long term care facilities need to be transferred to other facilities. Specific actions, decisions, and events that require the relocation include:

- Expiration or termination of a facility's provider agreement;
- Expiration or nonrenewal of a facility's State license;
- The facility's inability to provide care and related services because of fire, natural disaster, loss of staff, or another reason beyond its control;
- The facility's voluntary termination of participation in Medicaid and/or Medicare;
- Reclassification of the facility from a skilled nursing to an intermediate care facility; and
- Reclassification of patients to a different level of care.

B. Federal Program Requirement in Relocation of Medical Assistance Patients.--Federal financial participation may be claimed for facilities only if they are certified and participating in Medicaid under a valid agreement. Following termination by you FFP may be continued, for a period not to exceed 30 days if the State shows that it has made reasonable efforts to facilitate the orderly transfer of patients and residents to another facility. (See 42 CFR 441.11(b).) You may claim FFP for costs which are legitimately incurred in relocating Medicaid recipients.

You have the primary responsibility for relocating the patients and residents and for ensuring their safe and orderly transfer from a facility that no longer participates in Medicaid to a participating facility. This is because the State remains responsible for the care and services provided to public assistance recipients. The State's transfer policies must:

- Consider the nature and severity of the facility's failure to meet standards;
- Consider the availability of alternative facilities;
- Ensure that the situation is explained to the recipient and the recipient is permitted to exercise an informed choice as to whether he or she wishes to move and, if so, to which available facility;
- Provide that qualified personnel will assess patients' medical and psychological condition and needs, including the necessity to prepare the patient for transfer;
- Provide for adequate and appropriate transportation on the day the patient or resident is moved; and
- Apprise the receiving facility of the person's condition and needs.

C. State Relocation Activities.--In order for the relocation process to be orderly, the State action must meet at least the following requirements:

- The nature and severity of the facility's failure to meet required standards must be considered;
- The availability of suitable, alternative facilities must be considered;
- The situation must be explained to the individual recipient to permit him/her to exercise an informed choice as to whether he/she wishes to move (where that option is open) and to which facility he/she wishes to transfer;

- A review of the patient's medical and psychological condition and needs, including the need or potential need for preparing the patient for transfer, must be made by qualified personnel;

- Provision must be made for adequate, appropriate transportation on the day when recipients are to be moved; and

- The receiving facility must be fully apprised of the patient's condition and needs.

4658. GUIDANCE TO STATES FOR MEDICAID NURSING FACILITY (NF) REMEDIES

A. Background.--Section 1919(h) of the Act requires you to establish, by law (statute or regulation), remedies for nursing facilities (NFs) that do not meet the requirements of participation. Remedies should be designed to result in faster correction of deficiencies and ensure the health and safety of residents of NFs. You are to impose these remedies for NFs that are not owned by the State or those found noncompliant by HCFA's validation process.

If a NF does not meet one or more of the requirements, and the deficiencies immediately jeopardize the health or safety of the residents, take immediate action to:

- Remove the jeopardy and correct the deficiencies through the appointment of temporary management to oversee the operation of the facility and, at your option, impose one or more of the remedies available in subpart B, or

- Terminate the facility's Medicaid participation, and, at your option, impose one or more of the remedies available in subpart B.

If a NF does not meet one or more of the requirements and the deficiencies do not immediately jeopardize the health and safety of its residents you may:

- Terminate the facility's Medicaid participation,

- Impose one or more of the available remedies in subpart B,

- Do both.

Establish State remedies, by statute or regulation by October 1, 1989, as they are a condition of State plan approval for calendar quarters beginning on or after October 1, 1989.

B. Required State Remedies.--Specify the criteria as to when and how each remedy will be applied, the amounts of any fines, and the severity of each remedy. Design the procedures to minimize the time between identification of violations and final imposition of remedies. Denial of payment for new admissions, appointment of temporary management, and closure are remedies which may be imposed during the pendency of any hearing.

The criteria for all remedies are to provide for incrementally more severe fines for repeated or uncorrected deficiencies. In determining what action to take, consider the NF's compliance history, change of ownership, and the number and gravity of the deficiencies. You may also specify additional remedies that you can demonstrate are as effective in deterring non-compliance and correcting deficiencies as those which follow:

Follow regular procedures to amend your approved State plan to establish at least the following remedies:

1. Denial of Payment for New Admissions.--Deny payment for all Medicaid admissions after you give notice to the NF and the public that the NF is no longer in compliance with one or more of the requirements.

In accordance with §1919(h)(4) of the Act deny payment until the NF is in substantial compliance with the requirements of participation.

2. Civil Money Penalty.--Assess a civil money penalty, with interest, for each day the facility is or was out of compliance with one or more of the requirements of participation, even if the facility subsequently corrects its deficiencies and brings itself into full compliance. Establish criteria for assigning the amount of fines. Impose fines based upon the severity of the deficiencies and impose incrementally more severe fines in cases of repeated or uncorrected deficiencies. Apply all funds collected as a result of these civil money penalties to the protection of the health and property of residents of NFs that the State or HCFA finds deficient. Funds may be used for the cost of relocating residents to other facilities, maintenance or operation of a facility pending correction of deficiencies or closure, and for reimbursement of residents for personal funds lost. Civil money penalties may not be imposed during the pendency of any hearing.

3. Appointment of Temporary Management.--If you determine that there is a need for temporary management to ensure an orderly closure of a facility or while improvements are being made to bring a facility into compliance with all the requirements of participation, appoint temporary management to oversee the operation of the deficient NF and to protect the health and safety of its residents. Temporary management may be State personnel or private individuals with education and the requisite experience in nursing home administration and be licensed in accordance with State law. Do not discontinue temporary management that has been appointed for the period improvements are being made until you have determined that the NF has the management capability to ensure continued compliance with all the requirements of participation.

4. Closure of the NF and/or Transfer of Residents.--In the case of an emergency, close the NF or transfer the residents of the NF to other facilities or do both. For example, an emergency situation may relate to a provider's gross inability to provide care and related services because of fire, natural disaster, epidemic, or other conditions which endanger the health and safety of patients.

C. Alternative Remedies.--Include the specified remedies in subpart B in your approved State plan for any quarter beginning after October 1, 1989. However, you may establish remedies alternative to the specified State remedies (except for the remedy of termination) if, you can demonstrate to the satisfaction of HCFA that your alternative remedies are as effective in deterring noncompliance and correcting deficiencies as those under §1919(h)(2)(A) of the Act. For example, you may already have alternative remedies in place for the licensure program or for the Medicaid program under State law, such as:

- o Civil or administrative fines (different from the specified OBRA remedy);
- o Court-appointed receiver;
- o Conditional/provisional licensing, probationary license, or license revocation; and
- o Withholding of payments.

If so, summarize your past experience with alternative remedies indicating their effectiveness in deterring noncompliance and correcting deficiencies.

Provide the following types of documentation to indicate the effectiveness of your alternative remedies, such as:

- o Procedures for implementing the remedies including explanations of what type of deficiencies trigger the remedies, a method of ranking the seriousness of violations and corresponding remedies, timing of remedies and appeals and specific rules designating responsibility for the violation and liability for the remedies.
- o Identification of the agency responsible for ensuring imposition of the remedies and the amount of resources being devoted to this effort, including legal and other enforcement-related staff.
- o Method of evaluation and supporting data for alternative remedies that have proved to be effective in deterring noncompliance and correcting deficiencies including the number of facilities in evaluation and the rate of recidivism.

Alternatives to the specified remedies must be submitted under the established procedures for approval of State plan amendments.

D. Additional Requirements.--

1. Assuring Prompt Compliance.--If a NF has not complied with any of the requirements of participation within three months after the date the facility is found to be out of compliance with such requirements, impose a denial of payment for individuals admitted to the facility after the date of notice to the NF that it remains out of compliance for a three month period.

2. Repeated Noncompliance.--If you find, on three consecutive standard surveys, that a NF is providing substandard quality of care, then, regardless of any other remedies provided:

- Impose denial of payment for all new admissions to the NF, and
- Carry out onsite monitoring of the facility, on a regular basis, as needed, until the facility has demonstrated that it is in compliance with the requirements of participation and that it will remain in compliance.

E. Incentives For High Quality Care.--In addition to the remedies specified under §1919(h)(2) of the Act, you may establish in your approved State plan a program to reward nursing facilities that provide the highest quality care to Medicaid residents. The reward may be in the form of public recognition, incentive payments, or both. The expenses incurred in carrying out such a program shall be considered expenses necessary for the proper and efficient administration of the State plan under Medicaid (§1903(a)(7) of the Act).

Should you elect to use an incentive payment, the State plan amendment must define highest quality care, state the criteria to be met and measurements to be used in awarding an incentive payment. To be considered as "efficient" in the administration of the State plan, the incentive payment must be reasonable, as determined by the RO in its State plan review process.

F. Federal Financial Participation.--Reasonable State expenditures for the proper and efficient administration of the State plan, such as temporary management, closing a NF, transfer of residents to a new NF, and other expenses associated with implementing these remedies are subject to Federal matching payment at the rate of 50 percent. Establish procedures to prevent claiming FFP for expenditures which have been funded by the civil money penalties discussed in subpart B.